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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/667,077  | 09/18/2003  | Atushi Kajiyama      | 19941-000620US      | 6847             |
| 20350   | 7590        | 10/25/2005           | EXAMINER            |                  |
| TOWNSEND AND TOWNSEND AND CREW, LLP<br>TWO EMBARCADERO CENTER<br>EIGHTH FLOOR<br>SAN FRANCISCO, CA 94111-3834 |             |                      | SHEIKH, HUMERA N    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1615                |                  |

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/667,077

Applicant(s)

KAJIYAMA ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-11 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 14-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/23/05, 09/18/03</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION****Status of the Application**

Receipt of the Preliminary Amendment, Response and Applicant's Arguments, all filed 03/11/05 and the Information Disclosure Statements (IDS) filed 02/23/05 and 09/18/03 are acknowledged.

Claims 1, 3-11 and 14-20 are pending in this action. Claims 2, 12 and 13 have been cancelled. Claims 1, 3-11 and 14-20 are rejected.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-11 and 14-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,656,492 B2 ('492 Patent). Although the conflicting claims are not identical, they are not

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patentably distinct from each other because similar subject matter has been claimed in both the instant '077 application and the '492 Patent.

Claims 1, 3-11 and 14-20 of the instant application are drawn to a quick disintegrating tablet in buccal cavity, said quick disintegrating tablet comprising: (a) a plurality of drug-containing particles, wherein each particle comprises a bitter tasting drug and a pharmaceutical preparation carrier, wherein each particle has a mean diameter of approximately 50 to 250  $\mu\text{m}$  and an apparent specific gravity of approximately 0.5 to approximately 1.2; and (b) a saccharide.

Claims 1-20 of the instant application are drawn to a quick disintegrating tablet in buccal cavity, said quick disintegrating tablet comprising: (a) a plurality of drug-containing particles, wherein each particle comprises a bitter tasting drug of inferior fluidity, wherein the drug of inferior fluidity has an angle of repose of about  $41^{\circ} \sim 90^{\circ}$  and a pharmaceutical preparation carrier, wherein each particle has a mean diameter of approximately 50 to 250  $\mu\text{m}$  and an apparent specific gravity of approximately 0.5 to approximately 1.2, obtained by spray drying; and (b) a saccharide.

The only distinction observed between the instant application and the '492 Patent is that the instant application is generic in relation to the claims of the '492 Patent. The instant application is silent as to the recitation of a drug of 'inferior fluidity', silent as to the recitation of a particular 'angle of repose' and is silent as to how the tablet is obtained, such as by spray drying. Other than this distinction, the claimed subject matter between the instant application and the '492 Patent is quite similar.


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### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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October 13, 2005